UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LOUISIANA WHOLESALE DRUG CO., INC., On Behalf of Itself and All Others Similarly Situated, Plaintiffs, v. SANOFI-AVENTIS, SANOFI-AVENTIS U.S. LLC, and AVENTIS PHARMACEUTICALS INC., Defendants.	Civil No. 07-cv-7343 (HB) Hon. Harold Baer, U.S.D.J. Hon. Andrew J. Peck, U.S.M.J. ECF Case

DECLARATION OF ANNE K. FORNECKER, ESQ. IN OPPOSITION TO SANDOZ INC.'S MOTION TO QUASH SUBPOENA

ANNE K. FORNECKER, ESQ. hereby declares under penalties of perjury:

1. I am an associate at Garwin Gerstein & Fisher LLP, counsel for Plaintiff Louisiana Wholesale Drug Co., Inc. ("Louisiana Wholesale" or "Plaintiff") in this matter.

2. Louisiana Wholesale alleges that Sanofi-Aventis, Sanofi-Aventis US LLC, and Aventis Pharmaceuticals, Inc. (collectively, "Aventis" or "Defendants") filed an objectively baseless, "sham" Citizen Petition in order to delay FDA approval of multiple Abbreviated New Drug Applications ("ANDAs") filed by generic pharmaceutical manufacturers to market less-expensive AB-rated generic versions of the drug leflunomide, which is marketed by Defendants under the trade name Arava.

3. Movant Sandoz Inc. is one of five generic manufacturers that filed an ANDA seeking to market an AB-rated generic version of Arava.

4. Louisiana Wholesale also alleges that, although the FDA found

Defendants' Petition to be meritless, Defendants' Petition nevertheless successfully delayed FDA approval of the generic versions of leflunomide for approximately five months - - between March 31, 2005 (the date Defendants filed their Petition) and September 13, 2005 (the date the FDA rejected the "sham" Petition, and approved each of the five generic leflunomide products). Immediately upon receiving FDA approval, the AB-rated generic versions of leflunomide came to market, causing Defendants to lose approximately 80% of their $235 million annual U.S. Arava sales to AB-rated generic leflunomide within three months, saving direct purchasers tens of millions of dollars - - savings that should have begun to accrue five months earlier.

5. Lousiana Wholesale thus alleges that, as a result of their illegal conduct, Defendants fixed, raised, maintained, and/or stabilized the price of leflunomide at supra-competitive levels, and overcharged Louisiana Wholesale and other direct purchasers of Arava by millions of dollars by preventing them from purchasing earlier less expensive generic versions of Arava.

6. On December 5, 2007, United States District Judge Harold Baer, Jr. entered the pretrial scheduling order that was submitted by the parties on consent. Under that order, Plaintiff's class certification motion must be filed by January 31, 2008; fact discovery must be completed by May 1, 2008; and opening expert reports must be filed by May 15, 2008. *See* Pretrial Scheduling Order, attached hereto as Ex. 1.

7. In order to establish a section 2 violation, and demonstrate that Louisiana Wholesale and other direct purchasers are entitled to treble overcharge damages, Louisiana Wholesale bears the burden of demonstrating with evidence: 1) that Defendants' Petition was an objectively baseless "sham"; 2) that Defendants' Petition

caused the FDA to delay approval of one or more of the generic leflunomide products for some amount of time; and 3) the measure of overcharge damages Louisiana Wholesale and other direct purchasers of Arava suffered as a result of Defendants' unlawful conduct.

8. Louisiana Wholesale needs documents, electronic leflunomide sales data, and deposition discovery from the non-party generic leflunomide manufacturers, including Sandoz Inc., in order to establish its claim.

9. For example, in order to demonstrate that Defendants' Petition caused delay in FDA approval of the generic leflunomide products, Louisiana Wholesale will introduce evidence demonstrating that one or more of the generics were "ready, willing, and able" to come to market at some point prior to September 13, 2005. Based on Plaintiff's counsel's experience litigating similar pharmaceutical antitrust cases, a particular generic manufacturer's readiness, willingness and ability to come to market is determined by examining, *inter alia*, the manufacturer's: 1) ANDA, including any amendments or supplements thereto; 2) communications with the FDA regarding the approvability of the ANDA; 3) projections regarding (i) when it expected to receive final FDA approval; and (ii) launch quantities needed to fill the expected market for its product; and/or 4) product validation protocols and reports, which must be completed before a generic manufacture may launch its product.

10. In addition, in order to prove overcharge damages to the class of direct purchasers it seeks to represent, Louisiana Wholesale must establish the difference between the prices it and other direct purchasers paid for Arava and the prices it and other direct purchasers would have paid for generic leflunomide, had generic leflunomide been

available on the market earlier (*i.e.*, "but for" Defendants' illegal conduct). In order to determine that difference, Louisiana Wholesale needs sales and pricing data from the non-party generic manufacturers of leflunomide. That data will show what direct purchasers are paying now, which, in turn, informs what direct purchasers would have been paying had generic leflunomide been available on the market earlier. In addition, in order to show that antitrust impact is provable on a class-wide basis, Lousisiana Wholesale needs forecasts and projections of the unit and dollar sales Sandoz expected to make from launching generic leflunomide, which, by necessary implication, will show the savings direct purchasers of Arava could expect as a result of generic leflunomide competition.

11. Based on its genuine and pressing need for information to establish its claim, and move for certification of a class, Louisiana Wholesale served substantively identical subpoenas for documents and deposition testimony on: 1) each of the five manufacturers that filed ANDAs to market generic leflunomide, including Sandoz, Inc.; and 2) Prasco LLC, the generic manufacturer Defendants licensed to market an authorized generic version of Arava.[1]

12. No generic manufacturer, with the exception of Sandoz, has moved to quash Louisiana Wholesale's subpoena. With the exception of Sandoz, each of the other generic manufacturers, including Defendants' licensee, is cooperating with Louisiana Wholesale, and is expected to begin producing responsive documents shortly.

[1] Louisiana Wholesale also served a subpoena for the production of documents on Covington & Burling LLP, Defendants' outside regulatory counsel, which filed Defendants' Petition with the FDA. Covington & Burling has already produced some documents responsive to that subpoena.

13. Louisiana Wholesale has attempted to reduce Sandoz Inc.'s purported burden in responding to the subpoena to no avail.

14. During my telephone conversation of November 6, 2007 with counsel for Sandoz, Inc., Ed Reisner, Esq., I explained to Mr. Reisner how the discovery requests contained in the subpoena related to Louisiana Wholesale's allegations. In response to Mr. Reisner's concerns about the breadth of the subpoena, I explained, by way of example, that Sandoz's documents regarding its leflunomide ANDA, and any supplements or amendments thereto, are needed to evaluate the causation element of Louisiana Wholesale's allegations.

15. However, I also informed Mr. Reisner that Louisiana Wholesale was willing to discuss narrowing significantly the documents it would seek from Sandoz at the present time because of Louisiana Wholesale's need to get the requested documents very quickly (due to the short discovery schedule in this case), and its desire to reduce the burden on Sandoz, a non-party. Mr. Reisner stated that Sandoz had already begun its search for responsive documents.

16. I did not concede during the November 6, 2007 conversation, or at any other time, that the subpoena, as written, is overbroad. In my November 6, 2007 e-mail to Mr. Reisner, which he asked me to send to memorialize our conversation, I stated: "I am confident that we can narrow the requests in a manner that that will reduce the burden on your client, while ensuring that we obtain the documents we need to prove our case." *See* November 6, 2007 e-mail from Anne K. Fornecker to Edward Reisner, attached hereto as Ex. 2.

17. Prior to the November 9, 2007 telephone conversation between Mr. Reisner and various counsel for Louisiana Wholesale, I e-mailed to Mr. Reisner a copy of the protective order that has been entered in this case. That order applies to third parties. *See* Signed Protective Order, attached hereto as Ex. 3.

18. During the November 9, 2007 telephone conversation between Mr. Reisner and various counsel for Louisiana Wholesale, including myself, we again explained to Mr. Reisner how the discovery requests contained in the subpoena related to Louisiana Wholesale's allegations, and what Louisiana Wholesale must ultimately prove. In an effort to address Mr. Reisner's concerns about complying with the subpoena, Plaintiff's counsel identified five discrete categories of documents that Louisiana Wholesale would be satisfied to receive from Sandoz at the present time: 1) the ANDA correspondence file, including communications between Sandoz and FDA related to the approvability of Sandoz's ANDA; 2) launch projections for generic leflunomide; 3) validation reports and protocols; 4) manufacturing plans and projections; and 5) transaction-level sales data.

19. Plaintiff's counsel did not concede that the subpoena, nor the significantly narrowed requests, sought more information than Louisiana Wholesale needs to establish its claim. In fact, Plaintiff's counsel explained that we could not agree to issue a new subpoena requesting only those documents responsive to the narrowed requests specifically because, until Defendants' defenses emerge, it will remain unclear exactly what information Louisiana Wholesale will need in the future to establish its case, and defend its theories of liability, causation, and damages. Plaintiff's counsel explained that Louisiana Wholesale must be able to seek additional documents under the current

requests if it becomes necessary to do so in light of the information disclosed during the discovery process. Mr. Reisner said that he would relay our five narrowed requests to Sandoz.

20. On November 11, 2007, Mr. Reisner requested that Louisiana Wholesale withdraw its subpoena to Sandoz until Judge Baer decided Defendants' pending motions to dismiss. In response to that request, I informed Mr. Reisner that Louisiana Wholesale would not withdraw its subpoena to Sandoz in light of Judge Baer's October 4, 2007 ruling requiring all document discovery to proceed during the pendency of Defendants' motions to dismiss.

21. On or about November 14, 2007, Mr. Reisner requested that Louisiana Wholesale withdraw its subpoena to Sandoz because Sandoz likely could not have received FDA approval for its leflunomide ANDA much before September 13, 2005. Mr. Reisner also informed me that Sandoz was unwilling to produce all documents responsive to the five narrowed categories of documents and data Plaintiff's counsel identified to Mr. Reisner on November 9, 2007, even if Louisiana Wholesale withdrew its current subpoena, and issued a new subpoena limited only to those five areas. In light of Sandoz's position, I informed Mr. Reisner that I believed the negotiations to be at an impasse.

December 6, 2007 /s/ Anne K. Fornecker

CERTIFICATE OF SERVICE

I, Anne K. Fornecker, do hereby certify that on December 6, 2007, I served the foregoing DECLARATION OF ANNE K. FORNECKER, ESQ. IN OPPOSITION TO THIRD PARTY SANDOZ, INC.'S MOTION TO QUASH SUBPOENA on the following attorneys, in the manner specified below:

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By: /s/ Anne K. Fornecker